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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,539	05/01/2001	Lars Bjorck	100084.415US	4148

500 7590 05/23/2002

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/847,539

Applicant(s)

BJORCK ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18 and 20-22 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **Restriction**

1. Applicant's preliminary amendments filed on 5/01/2001 and 11/27/01 have been entered. Claim 19 has been canceled. Claims 3-5, 8-10, 13, 17 and 21 have been amended. Claims 1-18 and 20-22 are pending in the application.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12 and 18 drawn to a polypeptide, classified in class 530, subclass 350. Further election of invention is required.
- II. Claims 13-16, drawn to nucleic acid, classified in class 536, subclass 23.1. Further election of invention is required.
- III. Claim 17, drawn to a process for producing a polypeptide classified in class 435, subclass 69.3. Further election of invention is required.
- IV. Claim 20, drawn to a method of immunizing an individual classified in class 424, subclass 184.1. Further election of invention is required.
- V. Claim 21, drawn to an antibody, classified in class 530, subclass, 387.1. Further election of invention is required.
- VI. Claim 22, drawn to a method of treating an individual GAS infection with an antibody, classified in class 424, subclass 130.1. Further election of invention is required.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I/II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions I/II and V are drawn to different products which are different to each other structurally, functionally and biochemically. Invention I is drawn to a polypeptide which comprises amino acids and is distinct from antibody in invention V because antibody has a different structure, inherent avidity, affinity

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and specificity that a simple protein is not capable of expressing. Invention II is drawn to DNA, which is different from polypeptide and antibody in containing nucleic acid molecules.

4. Inventions III/IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions III/IV and VI are drawn to patentably distinct methods utilizing different reagents, steps and result in a different outcome. For example: Invention III is drawn to a method of producing a polypeptide which requires culturing a host cell that is transfected with a DNA whereas invention VI is a method of treating an individual GAS infection with an antibody which does not require culturing a host cell but requires an antibody to treat the infection. Invention IV is a method of immunizing an individual against streptococcus that requires a streptococcal protein in a pharmaceutical carrier capable of inducing an immune response, which does not require an antibody, or culturing a host cell and thus differs from inventions III and VI. Thus all these inventions are different having different modes of operation, different functions and different effects.

5. Inventions I and IV / VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (peptide) as claimed in invention I can be used in a materially different process of using that product such as immunochromatography for purifying antigens.

6. Inventions II and IV / VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

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product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (peptide) as claimed in invention II can be used in a materially different process of using that product such as hybridization.

7. Inventions V and IV / VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed in invention V can be used in a materially different process of using that product such as an immunoassay for identifying antigen in a sample.

8. Inventions III and 1 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product polypeptide can be made using a protein synthesizer, which is a different process.

#### **DISTINCT INVENTIONS**

9. Groups I- VI contain claims (1-18 and 20-22) reciting plurality of disclosed patentably distinct inventions as represented by different SEQ.ID.NOS 1-16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed SEQ.ID.NO for examination.

10. Because these inventions are distinct for the reason given above, have acquired a separate status in the art as shown by their different classification, and while searches may overlap they are not co-extensive, restriction for examination purposes as indicated is proper.

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11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 A.M. to 4:00 P.M. EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

5/22/02

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